PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bonnie DAVIS

Serial No.: 09/980,039 Group No.: 1627

Filed: August 6, 2002 Examiner: K. McMillian

For: USE OF ACETYLCHOLINESTERASE INHIBITORS ON THE MODULATION OF THE HYPOTHALAMIC-PITUITARY-GONADAL AXIS

Attorney Docket U 013729-7

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the document listed on the attached Form PTO-1449. A copy of the listed document is also attached.

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10*
*(When using Express Mail, the Express Mail label number is **mandatory**; Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☐ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. 1.8(a)

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TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office. to **(571)-273-8300**

EFS-WEB

☒ transmitted electronically

Date: May 5, 2010

Signature

Raymond A. DiPerna
(type or print name of person certifying)

The listed document was cited in an Office Action from the Japan Patent Office in connection with counterpart JP Application No. 2000-586332. An English-language version of the Office Action, indicating the degree of relevance found by the foreign office, is also attached.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a copy of the enclosed Form PTO-1449 be returned indicating that such information has been considered.

Please charge the required fee of $180.00 to cover the Information Disclosure Statement under 37 C.F.R. § 1.97(c)(2) to our Deposit Account No. 12-0425.

Respectfully submitted,

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(Translation) Mailed: January 5, 2010

NOTICE OF REASONS FOR REJECTION

Patent Application No.: 2000-586332

Examiner's Notice Date: December 15, 2009

Examiner: Yumiko Matsunami

Representative for Applicant: Mr. Takehiko Suzuye (and 3 others)

This application is rejected on the grounds stated below. Any opinion about the rejection must be filed within THREE MONTHS of the mailing date hereof.

REASONS

1. The invention(s) recited in the following claim(s) is(are) unpatentable as failing to satisfy the requirements under the main provision of Section 29 (1) of the Patent Law in the following respect(s).

2. The application fails to satisfy the requirements under Section 36 (4) of the Patent Law, on the grounds that the detailed description of the invention is defective in the following respect(s).

3. The application fails to satisfy the requirements under Section 36 (6) (i) of the Patent Law, on the grounds that the claims are defective in the following respect(s).

4. The application fails to satisfy the requirements under Section 36 (6) (ii) of the Patent Law, on the grounds that the claims are defective in the following respect(s).

REMARKS (refer to "References Cited" for particulars)

-Reason 1
-Notes

The inventions of Claims 1 to 10 are each directed to a method of treatment for a human being, and thus they do not represent "industrially applicable inventions."

-Reasons 2 and 3
-Notes

In general, it is difficult to grasp a compound itself merely by specifying a certain property thereof. Therefore, if a specification does not offer a clue for obtaining an active ingredient, such as a chemical structure, it becomes necessary to prepare

innumerable compounds and screen them to check whether a respective compound has the property in the process of obtaining an active ingredient necessary to carry out the invention, and such a process requires undue experimentation of a trial-and-error basis exceeding the level which can be usually expected from a person having ordinary skill in the art. Therefore, such a specification is judged to be not describing the invention clearly and sufficiently to such an extent that the invention can be easily carried out by a person having ordinary skill in the art based on the descriptions provided therein.

Based on the above, the specification of the present application will now be reviewed. The Detailed Description of the Invention, paragraph [0007] mentions donepezil, rivastigmine, galantamine, lycoramine and the analogs of galantamine and lycoramine, as specific examples of the acetylcholinesterase inhibitors which have a central effect and a duration of action of 1 to 100 hours. However, it does not provide a clue such as a chemical structure, to obtain an active ingredient other than the specified compounds, or it is not considered that the clue could be estimated by a person having ordinary skill in the art at the time when the present application was filed. Therefore, the active ingredients other than these and encompassed by the claims would not be grasped by a person having ordinary skill in the art, and thus it would require to prepare innumerable compounds and screen them for confirmation to carry out the invention, and such a process requires undue experimentation of a trial-and-error basis exceeding the level which can be usually expected from a person having ordinary skill in the art.

As described above, the Detailed Description of the Invention of the present application is no considered to describe the invention of Claim 1 clearly or sufficiently for a person skilled in the art to be able to carry the invention out, or provide a sufficient support.

This is also the case for Claims 2 to 10.

-Reasons 2 and 3
-Notes

The present invention recited in Claim 1 specifies an active ingredient by its function, and as a result, it encompasses compounds of various chemical structures. It is, in such a case, a common technical knowledge at the time of filing of the application that all of the compounds which have the function do not necessarily exhibit

a specific pharmacological effect. Therefore, pharmacological data, which may be results of a particular pharmacological test, or a theoretical explanation need to be provided in the specification for a person having ordinary skill in the art to be able to recognize that the compounds having the function exhibit the particular pharmacological effect.

However, despite the fact that there are compounds of various chemical structures included in the acetylcholinesterase inhibitors which have a central effect and a duration of action of 1 to 100 hours, the Detailed Description of the Invention does not provide any pharmacological test data which demonstrate a therapeutic effect against such diseases as failure of ovulation and luteal phase defect, or it does not provide pharmacological data or a theoretical explanation for a person having ordinary skill in the art to be able to generally recognize that all of the acetylcholinesterase inhibitors having the above-described function are effective for the diseases including failure of ovulation.

Further, Reference 1 listed below teaches that in the case where acephate is orally administered, acetylcholinesterase in the brain is blocked, and the concentration of luteinizing hormone in blood is decreased. With reference to this, it is not possible to conclude that all of the acetylcholinesterase inhibitors which have a central effect and a duration of action of 1 to 100 hours are effective for such diseases as failure of ovulation and luteal phase defect.

As described above, the Detailed Description of the Invention of the present application is no considered to describe the invention of Claim 1 clearly or sufficiently for a person skilled in the art to be able to carry the invention out, or provide a sufficient support.

This is also the case for Claims 2 to 10.

-Reason 4
-Notes

(1) Claim 1 contains the recitation "conditions what can benefit from stimulation of the hypothalamic-pituitary-gonadal axis", which is not clear as to what sort of conditions are specifically encompassed.

Therefore, the invention recited in Claim 1 is not definite.

This is also the case for Claim 2.

(2) Claim 1 contains the recitation "an acetylcholinesterase inhibitor having a

central effect and a duration of action of from 1 to 100 hours", which is not clear as to what sort of compositions are specifically encompassed.

Therefore, the invention recited in Claim 1 is not definite.

This is also the case for Claims 1 to 10.

(3) Claim 6 contains the recitation "said defect", whereas Claim 1 or 2, from which Claim 6 depends does not recite "defect". Thus, the recitation "said defect" is not clear as to what it means.

Therefore, the invention recited in Claim 6 is not definite.

References Cited:

1. Toxicology Letters, 1985, Vol. 24, p. 65-69

Note: It may be necessary to withhold part or all of a non-patent document where providing it would be against the law or would violate a contractual obligation.

Prior Art Search Report

Searched Field(s): IPC A61K45/00

DB Name	STN (CAplus, MEDLINE, BIOSIS, EMBASE)

Prior-Art Document(s):

FERTILITY AND STERILITY, 1999, Vol. 71, No. 4, p.652-657

Note: It may be necessary to withhold part or all of a non-patent document where providing it would be against the law or would violate a contractual obligation.

The result of this prior art search does not constitute the reasons for rejection.

If the applicant has questions regarding this Official Action or wishes to conduct an interview, please contact the following:

3rd Examination Department (Medical Science)
Examiner Ryoto Baba
TEL: 03(3581)1101, extension 3451

Ref. 1

引用非特許文献

特許出願の番号	特願２０００－５８６３３２
作成日	平成２１年１２月１５日
作成者	松波　由美子　　４０４３　４Ｃ００
発明の名称	視床下部－下垂体－生殖腺軸変調に於けるアセチルコリンエステラーゼ阻害剤の使用